IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Naparstek, Yaakov

Serial No. : 09/826,069

Filed : April 4, 2001

For : PEPTIDES FOR THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS AND METHODS OF TREATING SYSTEMIC LUPUS ERYTHEMATOSUS

Group Art Unit: 1644
Examiner: EWOLDT G. R.

Tel-Aviv, Israel
September 17, 2007

Hon. Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

DECLARATION UNDER 37 CFR SEC 1.132

I, the undersigned (inventor), Yaakov Naparstek, of 17 Davidson St., Jerusalem, Israel, hereby declare as follows:

Background Information

1. I obtained an MD degree in 1973, from the Hadassah-Hebrew University Medical School in Jerusalem, Israel.

2. I am employed at Hadassah University Hospital, Jerusalem, Israel, as Chairman of Medicine and as Professor of Medicine at the Hebrew University - Hadassah School of Medicine, Jerusalem, Israel.

3. I am Board certified in Internal Medicine, Rheumatology and Clinical Immunology and Allergy.

4. I have been a research fellow and a visiting Professor at the Weizmann Institute of Science, Rehovot, Tuft's University, Boston, The National Institute of Health, Bethesda and Stanford University, Stanford. I now serve as the Director of the Hadassah Clinical Immunology and Rheumatology Center.

5. I am also the incumbent of the Leifferman Chair in Rheumatology.

6. My main research interests are in the field of autoimmunity, SLE and autoimmune arthritis. In recent years, my research group has focused on the identification of the target antigens in SLE and in autoimmune arthritis and in the attempts to develop antigen-specific therapeutic modalities to those diseases.

7. I am the recipient of national and international awards, and the author of about 100 publications and chapters in books as well as many patents in the field of autoimmune inflammatory diseases.

8. Under my direction and control the following experiment is being undertaken, which has been approved by the Internal Review Board (Helsinki) and by the Israeli Ministry of Health:

**Phase I/II Clinical Trial with Luposorb™ Immunoadsorption Columns in Systemic Lupus Erythematosus (SLE or lupus) patients**

10 SLE patients will be recruited for treatment with a single Luposorb™ immunoadsorption session during routine plasmapheresis procedure. The Luposorb™ immunoadsorption column is an affinity adsorption column comprising R38 (VRT101) peptide. Patient screening prior to enrollment into the study is between 4 weeks up to 7 days prior to the day planned for plasmapheresis. Patients will be enrolled into the study on the plasmapheresis day and will undergo treatment of between 2-3 hours with the Luposorb™ column. The patients will then be followed up for 8 weeks after the Luposorb™ column procedure.

As of yet, two patients underwent treatment and completed the two-month follow-up period. The attached chart refers to the first patient only. The procedure was well-tolerated and no procedure-related adverse events were detected in either patient. As to preliminary efficacy, Figure 12 depicts the changes in antibody levels of the patient before treatment, after treatment and during the follow-up period. As shown in Figure 12, the level of anti-VRT (R38) antibodies decreased after the Luposorb™ apheresis and returned to the original levels after more than 5 weeks.

Overview Statement

9. The explanations contained in the following paragraphs address the uniqueness of the present invention over prior art solutions. The explanations do not replace the detailed background and technical details that were already provided in the patent application. These explanations are brought here to challenge the relevance of the Examiner's rejection statements, as stated in the Office Action (OA) dated January 30, 2006 and September 8, 2006.

10. As stated in paragraph 8 above, the continuing decline in antibody levels is an unusual and unexpected result, one that could not have been predicted from the disclosure of any of the references cited, nor any reference known to me.

11. I believe that the Examiner's rejection of the claims based on obviousness is overcome with the evidence of unexpected results.

12. This declaration is given in support of the patent prosecution efforts in the present application, before the USPTO.

13. I declare that all the statements made herein of my own knowledge are true, and that all statements made on information and knowledge are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed this 17 day of Sept 2007.

Yaakov Naparstek